

87 hours and 32 minutes. The staff spent on average 85 minutes in IV-PCA related activities, of which the nurse spent 98%. The average cost, including material and staff, for 24-hour usage of IV-PCA was €58.38. The patients thought that their pain was under control and they did not think it could be treated better, but they had some problem with pain when breathing or expectorating. According to the staff the IV-PCA system was easy to use for the patient but hindered their mobilization. **CONCLUSIONS:** IV-PCA involves many different roles and activities and intertwined sub processes. Therefore the whole system is complex and resource demanding. Comparisons of the results from similar studies at other hospitals will be very useful when optimizing the process.

PSY36

#### CHANGES IN RATES OF SICKLE CELL DISEASE-RELATED INPATIENT STAYS AND ASSOCIATED RESOURCE USE AMONG AFRICAN AMERICANS IN THE UNITED STATES FOLLOWING APPROVAL OF HYDROXYUREA

Candrilli SD<sup>1</sup>, Davis KL<sup>1</sup>, Balkrishnan R<sup>2</sup>, O'Brien S<sup>3</sup><sup>1</sup>RTI Health Solutions, Research Triangle Park, NC, USA, <sup>2</sup>University of Michigan, Ann Arbor, MI, USA, <sup>3</sup>The Research Institute at Nationwide Children's Hospital, Columbus, OH, USA

**OBJECTIVES:** Sickle cell disease (SCD) is an inherited disorder predominantly affecting people of African descent, and is characterized by the production of defective hemoglobin. Patients with SCD may experience intermittent and sometimes life-threatening complications often leading to frequent hospitalizations. Hydroxyurea (HU) is the only pharmacologic intervention approved (in 1998) for the treatment of adult SCD. This study expands upon previous research (Lanzkron et al, 2006) and generates national estimates of changes in SCD-related hospitalization rates and associated resource use in the United States (US) following approval of HU. **METHODS:** Discharge data from the 1996–2005 HCUP Nationwide Inpatient Samples for adult (≥20 years) African American (AA) patients with a primary SCD diagnosis (ICD-9-CM codes 282.6, 282.6x) were analyzed. Weighted, age-standardized hospitalization rates, and estimates of total charges and length of stay (LOS) were calculated for the 2 years before (1996–1997) and 8 years (1998–2005) following approval of HU. **RESULTS:** The age-standardized rate of SCD-related hospitalizations (per 10,000 2008 US adult AA population) has fallen appreciably from just before HU's approval in 1997 to 2005, from 17.3/10,000 to 13.8/10,000, a reduction of ~20%. During this period, the mean LOS has remained roughly unchanged (~6 days), though interestingly, mean total charges (in 2008 USD) incurred during an SCD-related stay have increased nearly 65%, from \$15,197 in 1997 to \$25,005 in 2005. **CONCLUSIONS:** We examined changes in rates of SCD-related hospitalizations and associated outcomes among AA patients following approval of HU for treatment of adult SCD. We observed a general decrease in the rate of hospitalizations over the first 7 years following approval of HU. However, little difference in LOS was seen, and total charges for this patient group have increased appreciably for unknown reasons. Clinicians and other decision-makers should be aware of the impact that HU appears to have on SCD-related inpatient outcomes.

#### SYSTEMIC DISORDERS/CONDITIONS – Patient-Reported Outcomes Studies

PSY37

#### IMPACT OF TOLVAPTAN ON SELF-REPORTED UTILITY SCORES IN HYPONATREMIC PATIENTS

Cyr PL<sup>1</sup>, Melnis M<sup>1</sup>, Ślawsky K<sup>1</sup>, Krassa H<sup>2</sup>, Czerwicz F<sup>2</sup>, Ouyang J<sup>2</sup>, Goss TF<sup>3</sup>, Verbalis JG<sup>4</sup><sup>1</sup>Boston Healthcare Associates, Inc, Boston, MA, USA, <sup>2</sup>Otsuka Pharmaceutical Development & Commercialization, Inc, Rockville, MD, USA, <sup>3</sup>Boston Healthcare Associates, Inc, Washington, DC, USA, <sup>4</sup>Georgetown Medical Center, Washington, DC, USA

**OBJECTIVES:** Cognitive and neurologic dysfunction, the most common physiological manifestations of hyponatremia, can significantly impair individuals' health-related quality of life (HRQOL). Therapeutic correction of hyponatremia should focus not only on normalization of serum sodium, but improvement of patients' functional utility as well. We examined the average change in utility scores from initiation of either tolvaptan therapy or standard of care (SOC) to day-7 and day-30 post-initiation. Standardized utility scores were derived from SF-12 scores from pooled SALT (Study of Ascending Levels of Tolvaptan in Hyponatremia) I and II data. **METHODS:** SF-12 scores were mapped to the EQ-5D and utility scores were derived using methodology developed by Gray, et.al, 2006. Mean change from baseline was assessed for both tolvaptan and standard of care (SOC) patient cohorts at day-7 and day-30, quantified as both absolute and percent change. Differences from baseline to day-7 and day-30 were assessed using a student's t test. **RESULTS:** All patients in the SALT trials had a baseline serum sodium <135 mEq/L. From baseline to day-7, the mean increase in utility score for tolvaptan patients (n = 180) was 0.084, compared to an increase of 0.032 for patients receiving SOC (n = 163) (p = 0.183). A statistically significant mean increase in utility was associated with tolvaptan use from baseline to day 30 post-therapy initiation compared with SOC (p = 0.005). The mean increase in utility score at day 30 for patients receiving tolvaptan (n = 150) was 0.108, whereas utility scores for patients receiving SOC (n = 164) had returned to baseline values by day-30, with a mean change from baseline of 0.001. **CONCLUSIONS:** Tolvaptan use for hyponatremia is associated with an increase in utility compared with SOC, evident at day-7 and statistically significant (p = 0.005) at day-30. Utility for tolvaptan patients increased from day-7 to day-30 while those for SOC decreased to baseline during this period.

PSY38

#### ELICITING HEALTH STATE UTILITIES FOR IMMUNE (IDIOPATHIC) THROMBOCYTOPENIC PURPURA: RESULTS OF A GENERAL PUBLIC BASED TIME TRADE-OFF SURVEY

Arnold DM<sup>1</sup>, Timmouth A<sup>2</sup>, Iskedian M<sup>3</sup>, Gafni A<sup>1</sup>, Deuson R<sup>4</sup>, Isitt J<sup>5</sup>, Mikhael J<sup>6</sup><sup>1</sup>McMaster University, Hamilton, ON, Canada, <sup>2</sup>Department of Medicine, University of Ottawa, Ottawa, ON, Canada, <sup>3</sup>Pharmideas Research and Consulting Inc, Oakville, ON, Canada, <sup>4</sup>Amgen, Thousand Oaks, CA, USA, <sup>5</sup>Amgen Inc, Thousand Oaks, CA, USA, <sup>6</sup>Mayo Clinic Arizona, Scottsdale, AZ, USA

**OBJECTIVES:** The objective of this study was to measure health state utilities associated with Immune Thrombocytopenic Purpura (ITP), as perceived by members of the Canadian general public. **METHODS:** An electronic version of the Time Trade-off (TTO) method was developed and administered to a sample of the general public in Canada. Twelve distinct health states were defined based on severity of bleeding, presence of other adverse events, and whether treatment was with romiplostim (a new thrombopoietin mimetic agent) or standard of care. Results from two 24-week randomized controlled phase 3 trials were used in developing health state descriptions. Pilot surveys were developed to ensure ease of use and to improve measurement characteristics of the final survey. A sample of 813 subjects was needed for power >0.90 and an alpha error of 0.05. Utility scores were reported as mean, median and range for each health state and compared using Dunn's post-hoc test. **RESULTS:** After two pilot tests on 126 participants, 821 adults [mean age 36.4 (range 22–80) years, 63% female] from Ontario, Canada, completed the TTO valuation survey. Mean (SD) utility scores ranged from 0.476 (0.271) for the most severe health state describing significant bleeding to 0.633 (0.282) for the health state depicting successful treatment with romiplostim without bleeding. Mean differences between the most severe bleeding health state and 5 other health states were statistically significant (p < 0.05 for each). **CONCLUSIONS:** The Canadian general public had decreased preference for the most severe ITP health states with significant bleeding. Respondents most preferred ITP health states with no bleeding combined with successful treatment with romiplostim. The utility scores derived from these 12 health states can be used as to inform cost-effectiveness models of romiplostim as a treatment for ITP in Canada.

PSY39

#### UTILITY MEASUREMENT STUDY FOR PATIENTS WITH CONTROLLED AND UNCONTROLLED PHENYLKETONURIA—A CASE STUDY FOR AN ORPHAN DISEASE

Stamuli E<sup>1</sup>, Trueman P<sup>1</sup>, Barth JH<sup>2</sup>, Chakrapani A<sup>3</sup>, D'Souza NA<sup>4</sup>, Galloway PJ<sup>5</sup>, MacDonald A<sup>3</sup>, Wildgoose JK<sup>6</sup>, Chauhan D<sup>7</sup><sup>1</sup>University of York, York, North Yorkshire, UK, <sup>2</sup>Leeds General Infirmary, Leeds, Yorkshire, UK, <sup>3</sup>Birmingham Children's Hospital, Birmingham, UK, <sup>4</sup>Princess of Wales Hospital, Bridgend, Wales, UK, <sup>5</sup>Yorkhill Children's Hospital, Glasgow, UK, <sup>6</sup>St Lukes Hospital, Bradford, UK, <sup>7</sup>Merck Serono Ltd, Feltham, Middlesex, UK

**OBJECTIVES:** Phenylketonuria (PKU) and its dietary management have a substantial effect on quality of life (QOL) of patients and their families. There is little published research that quantifies these effects in this orphan disease. The study explores the impact of PKU and its severity on QOL by eliciting utilities from a sample of general population. **METHODS:** Health state descriptions were developed for children and adults from the literature and expert interviews (n = 3) and validated by different clinicians (n = 3). Health states for children were: controlled (designated by target phenylalanine levels) by diet or medication for severe or mild/moderate disease; uncontrolled irrespective of severity. Adults' states were: controlled by diet or medication; uncontrolled. 100 participants across four UK centres were presented randomly with health state descriptions which were valued using the EQ-5D questionnaire and TTO (Time-trade-off) exercise to produce utility values. **RESULTS:** For both children and adults health states, the highest utility was attributed to health states controlled by medicine for both the EQ-5D and TTO (Children: severe 0.71–0.91, mild/moderate 0.76–0.94, Adults: 0.79–0.83). The uncontrolled state is associated with a lower utility score across groups and instruments. The EQ-5D scores were lower compared to TTO (particularly for children where parents found difficulty in trading off length of life). The addition of a drug, adjunct to diet, had larger effect on the EQ-5D score. Utilities for children were higher than adults across methods **CONCLUSIONS:** This small study provides evidence of a QoL impact of phenylketonuria. In both TTO and EQ-5D valuations, utilities were higher in controlled compared to uncontrolled state in children and adults. The addition of an effective drug, adjunct to diet, to control PKU improved utility further. This research also provides insight into the difficulties measuring utility in orphan diseases where natural history is hard to define.

PSY40

#### A COMPARATIVE STUDY ON HEMOPHILIA TREATMENT AND MEDICATION BY THE PRESENCE OF INHIBITORS IN SOUTH KOREA

Kim JY, Lee EK

Sook Myung Women's University, Seoul, South Korea

**OBJECTIVES:** Hemophilia is a rare and intractable disease. Although it is a rare, the per-capita cost of the disease covered by health insurance budget is high. The generation of patients with inhibitors incurs higher expenses and is prone to complications. This study compares treatment and medication pattern by the presence of inhibitors. **METHODS:** A survey was conducted for 99 patients without inhibitors and 32 patients with inhibitors. Age distribution of patients was similar to the actual distribution of patients. The rate and frequency of hospitalization, treatment-related tests, adjuvant treatment and the rate of complications were examined. In addition, patients' age, drugs in use, the number of hospital visits, and the number of drug administration